

JAN 02 2002

NADA 117-532

Ms. Beverly D Streeter, Specialist
Pharmaceutical Regulatory Affairs
Boehringer Ingelheim Vetmedica Inc.
15 Th & Oak St P.O. Box 338
Elwood, KS 66024
USA

Dear Ms. Streeter,

This is in reference to your two submissions (a Special DER dated September 7, 2001, and an Annual DER dated September 10, 2001), concerning Acepromazine (Injection & Tablets), NADA 117-532. The submissions include "Product Information Sheet" for your new distributor, which is determined to be a Promotional Labeling as stipulated under 21 CFR 202.1(I)(2).

We note that the promotional piece fails to provide full disclosure information, i.e., the reproduction of a full package insert as required by 21 CFR 201.105(d)(1). The information included in the piece in question is not reflective of the currently approved insert. We also note that the piece discusses all the benefits of the product but does not include the risks associated with the use of this product such as: prolonged depression/restlessness, hypotension, the additive effects when used in combination with other depressants, and contraindications, warnings, etc., in the running text of the piece in the same language and emphasis as provided in the approved labeling.

As a sponsor, Boehringer Ingelheim Vetmedica, Inc. has the ultimate responsibility to see that actions of the company or its distributor/agents do not violate the conditions of approval of the New Animal Drug Application. We request that you give due consideration and attention to the promotional practices of the distributors of your products to ensure that their promotional materials comply with the requirements of the Act and the promotion and advertising regulations. We request that you have your distributor immediately stop the usage of the above cited material.

Please inform us of your intentions as soon as possible or in any event within 30 days of the receipt of this letter. If you have any questions, you may contact us at (301)827-6642.

Sincerely yours,

Mohammad I. Sharar, DVM, M.Sc.
Team Leader, Marketed Product Scientific
and Regulatory Review Team II, HFV-216
Division of Surveillance
Center for Veterinary Medicine